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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/334,325	06/16/1999	STEWART A. CEDERHOLM-WILLIAMS	CV0276A	5209

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EXAMINER	
CHEN, SHIN LIN	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 12/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/334,325	CEDERHOLM-WILLIAMS, STEWART A.	
	Examiner	Art Unit	
	Shin-Lin Chen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 13-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 13-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment filed 9-22-04 has been entered. Claims 1 and 13-16 are pending and under consideration.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1 and 13-16 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for transforming a cell *in vitro* by applying a nucleic acid to the cell and then adhering a pliable, adhesive fibrin gel to said cell so as to entrap the nucleic acid in the fibrin gel to the cell, does not reasonably provide enablement for a method of transforming a cell *in vivo* by applying a nucleic acid to the cell and then adhering a pliable, adhesive fibrin gel to said cell so as to entrap the nucleic acid in the fibrin gel to the cell and transform said cell. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims and is repeated for the reasons set forth in the preceding Official action mailed 4-19-04. Applicant's arguments filed 9-22-04 have been fully considered but they are not persuasive.

Applicant argues that the claims are directed to transforming a cell not gene therapy and transforming a cell is not unpredictable. Applicant further argues that transforming nucleic acids are well-known and transforming a cell in vitro is enabled (amendment, p. 2-3). This is not

found persuasive because of the reasons set forth in the preceding Official action mailed 4-19-04. The claims are directed to a method of transforming a cell *in vitro* or *in vivo*. Although the amendment filed 9-22-04 amends the title to read "Fibrin Sealant as a Transfection/ Transformation Vehicle", the specification states "[I]n gene therapy, one seeks to transfect or transfonn cells of a certain cell type, such as liver cells, pancreatic cells, lung cells, muscle cells, leucocytes and the like, to insert an gene to correct a genetic defect or otherwise provide a helpful function" and "[S]imilarly, nucleic acid-based vaccines seek to induce a percentage of cells to produce immune-reaction inducing polypeptides, to induce an antibody-based or cellular-based immune response" (see specification, page 1, lines 23-25 and 29-31). The claims read on applying a nucleic acid to cells in vivo so as to transform cells and the transformation of cells in vivo must have a use, which is to provide therapeutic effect in vivo. The sole use of transforming a cell in vivo as stated in the specification is for gene therapy or as a nucleic acid-based vaccine, which is considered a type of gene therapy. Therefore, the claims read on gene therapy in vivo. As discussed in the preceding Official action mailed 4-19-04, the state of the art for gene therapy *in vivo* was unpredictable at the time of the invention and the claims are not enabled for a method of transforming a cell *in vivo* by applying a nucleic acid to the cell and then adhering a pliable, adhesive fibrin gel to said cell via various administration routes so as to provide therapeutic effects in an individual for a particular disease or disorder. Further, the specification also fails to provide adequate guidance and evidence for how to administer a pliable, adhesive fibrin gel to a cell having administered nucleic acid in a subject such that target cells in said subject are transformed with said nucleic acid. The specification fails to provide

adequate guidance for how to deliver the pliable, adhesive fibrin gel before the fibrin gel is polymerized to target cells in a subject for transformation of said cells.

Applicant argues that the 35 U.S.C. 112 first paragraph rejection is for want of utility and the Office does not provide scientific explanation to doubt the asserted utility. Applicant further argues that the Office's assertion is a belief that the nature of a fibrin gel would somehow disable or interfere transformation and the office should provide reasoning behind such assertion according to "The Office's Utility Examination Guidelines" (amendment, p. 3-5). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 4-19-04 and the reasons set forth above. It should be noted that this is a 35 U.S.C. 112 first paragraph enablement rejection but **not** a 35 U.S.C. 101 Utility rejection. The 35 U.S.C. 112 first paragraph enablement rejection does not concern whether there is a utility of the claimed method rather it concerns whether the claimed method is enabled. The enablement rejection does not state that a fibrin gel would somehow disable or interfere the transformation of cells. The Official action mailed 4-19-04 provides a scientific reasoning for why the claimed method is not enabled. The Official action states that the specification fails to provide adequate guidance for how to deliver the pliable, adhesive fibrin gel before the fibrin gel is polymerized to target cells in a subject for transformation of said cells. It was known in the art that the pliable, adhesive fibrin gel will polymerize quickly. Since the pliable, adhesive fibrin gel will polymerize in a short period of time, one would need to deliver said fibrin gel to target cells at various locations in a subject before polymerization of said fibrin gel so as to transform said target cells with a nucleic acid. This would be problematic because there is not much time for one skilled in the art to deliver the pliable and adhesive fibrin gel to the target cells inside the body of the subject,

such as cells in liver, kidney, heart intestine, stomach etc, before the pliable and adhesive fibrin gel is polymerized. There is no evidence of record that shows transformation of target cells in a subject with any nucleic acid via administering the nucleic acid to the cells first and then administering the pliable and adhesive fibrin gel to said cells. Thus, claims 1 and 13-16 remain rejected under 35 U.S.C. 112 first paragraph.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for this group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Shin-Lin Chen, Ph.D.

SHIN-LIN CHEN
PRIMARY EXAMINER